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Joseph P. Errico

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SPINE MP

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

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3738

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/663,493	Applicant(s) ERRICO ET AL.	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-12, 14-20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-12, 14-20 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 1/15/10 have been fully considered but they are not persuasive. Applicants present arguments with respect to the drawing objection and state that an alternative insertor/impactor described in paragraph 153 suggests the claimed invention is shown. However, the Examiner is not persuaded because in viewing Figs. 78,80 there is a set of angles on the plates and tool that correspond to one another to establish matching contours. However, in these drawings there is only one set of surfaces (180a,e,f) that allow for the tool and plates (168a,b) to engage. Both plates (168a,b) show the plate contour rounding from the surfaces 180a and 180f such that no other positioning of the tool would be permitted on such plates but the single matching position as seen in Figs. 78,80. The Examiner does acknowledge that paragraph 155 of the specification suggests that additional angulated surfaces can be placed on the surfaces of the baseplates. It is requested that a formal drawing be illustrated to show such claimed such matter. In response to the remarks regarding the 112 rejection, the Examiner agrees that there may be support for a plurality of engagement positions, but disagrees that there is a plurality of ways to engage the tool and implant together. The disclosure has presented one way. In consideration of the comments, the Examiner presents further reasons below in the 112 rejection with suggestions for Applicants to consider in order to clarify this feature being claimed.

With respect to the arguments against the rejection over Gill in view of McGahan and Jackson, Applicant argues that Gill only suggests one “way” to engage the tool with the baseplates. In response to applicant's arguments against the Gill reference individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the suggested combination, the Examiner relied on McGahan for the engagement contours being angled as claimed. While Gill can be said to suggest matching contours, it did not explicitly state “angles”, thus, McGahan was relied on for the surfaces of the tool to be angled and the angled matching perimeter surfaces of the plates. Additionally, Jackson taught the matching angled upper and lower surfaces of a tool that engaged matching upper and lower angled surfaces of the baseplates, which Gill appeared to be silent about also, but had these matching contours also. Thus, the Examiner has established a proper *prima facie* case of obviousness. Applicants have failed to state in the remarks where the corresponding structure of the baseplates is in the claims that permit the “plurality of ways” to be accomplished. Claimed functions must be supported by sufficient structure in the claims in order to enable the function to occur. Gill as modified with McGahan can be said to disclose the claimed three flat perimeter surfaces converging to form two protruding corners that engage the three flat surfaces that converge to form recessed corners on the distal end of the tool of Gill as modified with McGahan. In addition, with the teaching of Jackson, it can be said that the structure of the claimed tool and baseplate

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engagement is met by the modification. Applicants arguments that the tool and baseplates of Gill as modified with McGahan and Jackson is not capable of being considered to be an engagement of a "plurality of ways" since Gill is alleged to not have the sufficient structure for the engagement to be done in a "plurality of ways". This is not persuasive because what is this "sufficient structure" that the tool and baseplates of Gill when modified with McGahan and Jackson do not possess? The claims only require three flat surfaces with corresponding protruding corners and recesses clearly taught by McGahan. Additionally, it can be said that the engagement of the tool and baseplates is capable of being oriented *together* in both the left and right anterolateral approaches.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the upper and lower angled surfaces of a spacer at the distal end of the tool **being engageable in a plurality of ways** with corresponding angled surfaces of baseplates of an implant must be shown or the feature(s) canceled from the claim(s). According to the claimed embodiment, there is only one way for the tool to engage the baseplates, i.e. between the baseplates. It is understood that the claimed embodiment is Figs. 71-82. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

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replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8,10-12,14-20,22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a tool that is capable of being placed at a plurality of positions about the perimeter of an implant having baseplates, the disclosure does not reasonably provide enablement for “ways” other than the single positioning of the tool between the baseplates at the various locations. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. It is acknowledged that the tool can be placed at various locations about the perimeter of the baseplates, but the engagement of the tool and baseplates is only accomplished one way via a contact of the angled surfaces in one position between the baseplates. Thus, the interpretation of “ways” which can mean alternative tools or means to attach the tool and baseplates in a coupled fashion is not disclosed. Additionally, Applicants have not provided a clear illustration (as discussed above) of the implant **160** and its baseplates **168a,b** that it can have the tool positioned at various locations. Clarification is required.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8,10-12,14-20,22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill et al. (6117637) in view of McGahan et al. (WO 01/62191) and Jackson (6821298). Gill et al. disclose (Fig. 1a) an intervertebral spacer device **20** having a first baseplate **22** and a second baseplate **24**, with each including upper and lower surfaces, and a perimeter. It can be seen that the first and second baseplates are mounted to one another such that they can articulate relative to one another. Gill also discloses (Fig. 14a) a manipulation tool **70** having a correspondingly distal surface **76** that when engaged with the perimeter of the baseplates, rotation of the baseplates

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relative to the corresponding distal surface of the manipulation tool is prevented by interference between the perimeter of the baseplates and the corresponding distal surface of the manipulation tool. It can also be seen the manipulation tool further includes a spacer **84** protruding outwardly from the distal surface of the tool and has an upper surface and a lower surface. It is noted that Gill et al. show (Figs. 6,14b) the baseplates and tool have corresponding surfaces that appear angled, but do not explicitly state the contour of these surfaces. McGahan et al. illustrates (Fig. 15b) a spinal orthopedic set with a spinal implant **10** with angled perimeter surfaces having a central flat surface **22** flanked by two flat corner perimeter surfaces **18**, **26** that correspond to the angled distal end of the tool having central surface **128** and two flanked flat surfaces **126**, **130** to engage the implant. McGahan teaches that angled perimeter flat surfaces are provided to prevent rotation of the implant when inserting with the tool, page 12, lines 21-24. McGahan also shows (Fig. 22B) a difference in dimension of the implant surface and the tool engaging surface. McGahan show (Figs. 29A,B) another insertion tool and implant where the corresponding angled surfaces comprise a central flat surface flanked by two adjacent flat surfaces and thus form corners. However, Gill et al. also fail to disclose the spacer having angled upper and lower surfaces. Jackson teaches (Fig. 9) a spinal device that has a spacer **103** having upper and lower angled surfaces **133**, clearly seen in Fig. 12. It would have been obvious to one of ordinary skill in the art to use angled perimeters that correspond for a tool and spinal plate structure as taught by McGahan et al. with the implant and tool of Gill et al. and also use angled upper and lower surfaces for the spacer as taught by

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Jackson with the spacer portions of Gill et al. such that by using the modified angled surfaces that match or correspond when engaged together do not allow for movement. Such a modification only involves routine skill in the art and would have predictable results. Any non-angled surfaces, i.e. curvate have the risk of sliding and would not be desirable when a surgeon is inserting the implant into the patient's vertebral space and thus the modification of using angled surfaces by the teachings of McGahan and Jackson provide an obvious expedient to thus provide the first baseplate to be lordotically angled with respect to the second baseplate as the lower surface of the first baseplate is held against the upper angled surface of the spacer in a nonmovable engagement. With respect to claims 1,14-15,18-20,22 as best understood, the Examiner is interpreting the limitation of "engagement in a plurality of ways" such that the Gill modified tool angled spacer when engaged with the corresponding angled surfaces of the baseplates can be positioned together in a plurality of ways such that the surgeon when accessing the spinal space can insert left anterolateral or right anterolaterally or anteriorly. Thus the baseplates and tool of Gill as modified with McGahan and Jackson are fully capable of being positioned in a plurality of ways based on the decision of the surgeon. The Examiner is entitled to give terms in a claim its plain meaning as interpreted by one of ordinary skill in the art. It is noted that the specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d

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1851,1854 (Fed. Cir. 2001) and MPEP 2111.01. No clear definition is evident for the term “ways” and thus, the fact that the surfaces of Gill’s baseplates and corresponding surfaces of the tool as modified with McGahan and Jackson meet the structural limitations as claimed, it can be interpreted that the plurality of ways can be accomplished just by orienting the tool and baseplates of Gill in the claimed orientation approaches together.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738